IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO WAVE 8 CASES IN EXHIBIT A OF PLAINTIFFS' DAUBERT MOTION	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

PLAINTIFFS' REPLY IN FURTHER SUPPORT OF DAUBERT MOTION TO PRECLUDE OR LIMIT OPINIONS OF DR. MILES MURPHY

In further support of their Motion to exclude certain opinions and testimony of Defendants' expert, Miles Murphy, M.D. ("Dr. Murphy"), Plaintiffs state as follows:

LEGAL ARGUMENT

I. Dr. Murphy's Opinions Concerning Prolift Warnings

Dr. Murphy's opinions are entirely subjective, without reference to any objective source or standard other than stating the IFU and Patient Brochure is consistent with his own personal standards:

> Q. The standard you just gave me of what you think should be in an IFU, is that just your own personal standard?
>
> A. That was my opinion of what makes sense to be in an IFU.
>
> Q. That's your own personal opinion not based on any other information you've read or seen, correct?

A. Correct.

Q. It's your own personal viewpoint your own personal standard, correct?

A. Yes.

Q. With regard to what would need to be included in the patient brochure with regard to risks and benefits to the extent you've drawn any opinions in your report on that again is that based on your own personal standard your own personal opinion?

A. I do not -- I think the answer is yes because I don't know any sort of legal guidelines by which patient brochures are supposed to be produced.

Q. And do you have any information you can share with me now that you gleaned from any Ethicon documents or testimony where you saw what Ethicon thought the standards were to determine whether or not a risk or a benefit would need to be described and how it should be described in a patient brochure?

A. I don't recall seeing any standards that they refer to.

Q. Did you see any testimony in any deposition that you are relying on as you sit here now with regard to what needs to be included in an IFU?

A. I do not recall seeing anything like that.

Q. So again with regard to the IFU and the contents of the IFU whatever opinion yon are drawing is just based on your own personal opinion not based on what any other standards may be or what anyone else might think, correct?

A. Right it's my expert opinion not based on outside information.[1]

"While an expert who is a urologist may testify about the specific risks of implanting mesh and whether those risks appeared on the relevant IFU, the same expert must possess additional expertise to offer expert testimony about what information should or should not be included in an IFU." Wise v. C. R. Bard, Inc., No. 2:12-cv-1378, 2015 WL 521202, at *14 (S.D. W. Va. Feb. 7, 2015). Because Dr. Murphy is not an expert in the development of warnings labels and does not

[1] Miles Murphy, M.D. 11/30/2012 Dep. Tr. at 350:2-351:14, attached as Ex. A.

possess the additional expertise to offer expert testimony about what an IFU should or should not include, he is not qualified to offer expert testimony about warnings relating to the Prolift Device.

II. What Ethicon "Knew" or "Thought"

Dr. Murphy conceded in his deposition that he was unaware of what medical affairs at Ethicon knew or did in order to obtain information regarding the potential risks and complications in connection with the Prolift Device:

> Q. Do you know what specific data was available to Ethicon as of February, March 2005 when they were actually now launching the Prolift®, what they actually were relying on at the time they made the decision, yes, it's safe and effective, yes, we can market it?
>
> A. I do not know what they were relying on.
>
> Q. Since you don't know specifically what they're relying on, you're not going to offer any specific opinions about whether that data was sufficient or not; fair statement?
>
> A. I'm happy to offer opinions on the data that was present. I'm not going to make an expert opinion as to what Ethicon was relying on. I have no idea what they thought was important.
>
> Q. My question is this: Since you don't know what Ethicon specifically was relying on when they made that decision to launch the Prolift®, you wouldn't be offering me an opinion about whether something you're not familiar with was reasonable or not, correct?
>
> A. Not unless you give me some information about what they knew and what they were relying upon, and then I'd be happy to make an opinion on it.
>
> Q. Well, this is my chance to ask you what you know and what your opinions are. So as you sit here now, you have no opinion on that, correct?
>
> A. Correct.[2]
>
> * * *

[2] Ex. A at 114:7-115:13.

Q. So you're basically saying that based on that language, you would assume that patients would figure out that when they read that language, that is communicating to them that the complications they can suffer from the Prolift® can be life changing and that those complications can result in incapacitating pelvic pain, dyspareunia and large-scale erosions that can be exceedingly complex and not easily resolved?

A. I don't think that a patient brochure is -- the point of it is to explain every potential possible thing that can happen to a patient. I think what the point of a patient brochure is is to facilitate a discussion between the patient and her surgeon regarding the surgery that that surgeon is about to perform upon the patient, and, yes, I think that is adequate.

Q. When you say that that is adequate, that, as I think we described earlier or discussed earlier, that is your personal viewpoint, not based on any standards that Ethicon was utilizing or any other standards you can point to for what needs to be communicated in a patient brochure, correct?

A. I'm not holding myself out as a expert on regulatory issues within Gynecare, correct.

Q. Are you holding yourself out as an expert with regard to what needs to be communicated in the patient brochure?

A. Yes.

Q. What standards, other than your own personal viewpoint, what source of information are you relying on besides that?

A. My standards as a caring, compassionate physician.

Q. But it's your own personal standard, correct?

A. And I think that's shared by the vast majority of doctors out there.

Q. But you've never studied that question, and you can't point to anything to confirm that, correct?

A. I have no publications on that.[3]

* * *

Q. Am I correct that you reviewed very little by way of documents indicating what the people within medical affairs at Ethicon thought at any particular point in time?

[3] Ex. A at 450:14-452:3.

A. What I'm saying is I got stacks of documents within the last two weeks that were about 2 feet high, and I have only gotten through a small percentage of that.

Q. As you sit here now, you don't feel that you have a good understanding of what the people in medical affairs at Ethicon thought with regard to mesh shrinkage, erosion or other topics?

A. If you read my report, I don't think anywhere do I mention what the people in medical affairs at Gynecare knew or didn't know.[4]

If Dr. Murphy doesn't know what Ethicon knew, or what information they relied upon in bringing the Prolift Device to the market, how can he give an opinion that Ethicon acted reasonably or met the standard of care? Because Dr. Murphy relied on his own personal standards and is not familiar with what Ethicon knew or did not know concerning the dangers of the Prolift Device or what standards Ethicon itself applied – he cannot give any opinions as to whether Ethicon acted reasonably or met the standard of care.

III. Dr. Murphy's Other Opinions Regarding Ethicon's Prolift Device

Plaintiffs incorporate by reference the arguments made in Plaintiffs' Motion.

IV. Dr. Murphy's Reliance on Materials that he Did Not Read or Rely on to Write his Prolift Report

As explained in Plaintiffs' Motion, Dr. Murphy's expert report includes an extensive list of reliance materials, yet he acknowledged throughout his deposition that he has **not** reviewed many of the materials and does not know what most contain. Of particular importance, he admitted:

1. The list of "Additional Materials" was included so that he could say he listed them in case he wanted to mention them at trial.

2. He did not rely on all the "Additional Materials."

[4] Ex. A at 476:1-15.

3. He would be unable to go through the list of Additional Materials and identify the things he looked at versus the things that were listed in case he wanted to reference them later.

4. The items referenced in the bibliography is the universe of items he thought were important when he drafted the report, and thus were referenced.

5. Internal Ethicon documents were only listed because they were given to him in case he would need to reference them when he testified.

6. He never asked what internal documents had been produced by Ethicon on discovery, and he did not request any.

7. He read less than 20% of all the materials listed at the end of his supplemental report.[5]

Since he did not review the materials set forth above – any questions he was asked, or may have been asked, would be a waste of time as can be seen throughout his deposition. A few examples of such questioning can be demonstrated by the following examples:

Q. I'm looking now at the additional list of materials, and go to the point where it says other documents after the list of articles. Turn forward a couple pages.

A. Forward, meaning keep going?

Q. Yes. Go to the page where at the top the first document listed is Ethicon memo to R. Roussesau from Thomas Barbolt.

A. I see it.

Q. Have you reviewed that document?

A. I don't recall reviewing it.

Q. Go to the next document Ethicon Report, PSE Accession No., et cetera, is that a document you reviewed?

A. I don't recall.

Q. Go to the third document, Ethicon March 5, 2001 memo, et cetera, is that a document you reviewed?

[5] Ex. A at 17:16-29:21; 133:15-134:9.

A. I don't remember reviewing that.

Q. The fourth document listed here, Ethicon December 2, 2001 memo to Maggie D'Aversa, et cetera, is that a document you reviewed?

A. I don't remember reviewing it.

Q. The next document listed, Ethicon Final Report PSE Accession No., et cetera, a 28-day tissue reaction study, is that a document you reviewed?

A. I don't remember. I don't recall reviewing that.

Q. The next document, Ethicon Final Report, PSE Accession No., et cetera, 14-day adhesion prevention study, did you review that document?

A. I don't recall reviewing that document.

Q. Go to the next document listed, which is Ethicon Report PSE Accession No. 02-0579, Project No. 48010, et cetera, did you review that document?

A. I may have.

Q. Is there anything you can tell me about it now that's of any significance?

A. No.

Q. Go to the next document, Ethicon report dated 1/19/05 Biocompatibility Risk Assessment, is that a document you reviewed?

A. Again, I may have. It looks familiar, but I don't -- I couldn't tell you anything substantive about what it said.

Q. Next document, Ethicon Completion Report: BE-2004-1606, design verification, et cetera, is that a document you reviewed?

A. I don't recall reviewing that.

Q. The next document, clinical study report evaluation of the TVM technique for treatment of genital prolapse dated June 27, 2006, is that a document you reviewed?

A. That looks familiar.

Q. Is there anything you can tell me about it in terms of whether there's anything of significance in it, as you sit here now?

A. Significance in relation to what?

Q. Your opinions?

A. I can't recall anything.

Q. Go to the next document, clinical study report evaluation of TVM technique for treatment of genital prolapse dated June 28, 2006, did you review that document?

A. I may have, but, again, I would give you the same answer as the previous document.[6]

Consequently, Dr. Murphy should be precluded from relying on any such documents without Plaintiffs having the opportunity to re-depose him on these materials.

V. Dr. Murphy's Opinions about the TVT and TVT-O Devices are Inadmissible.

Defendants' argue in its Response in Opposition to Plaintiffs' Motion to Preclude or Limit Opinions of Miles Murphy, M.D. that Plaintiffs failed to identify with any specificity precisely what opinions they seek to exclude. Ds' Mem. At 8. As discussed in Plaintiff's Motion, Dr. Murphy's TVT and TVT-O general report never directly states his opinions with any specificity. Nor does he address the objective standards or criteria in forming his opinions and, thus, follows no scientific methodology that can be discerned.

Rule 26(a)(2) of the Federal Rules of Civil Procedure imposes specific requirements for the disclosure of expert testimony. Specifically, experts are required to provide a written report detailing the opinions the expert will offer at trial, the basis and reasons underlying those opinions, the facts and data considered while forming them, and a variety of other information pertaining to the expert's background and qualifications. Fed. R. Civ. P. 26(a)(2)(B). Dr. Murphy made sweeping, general statements regarding the history and treatment of stress urinary incontinence, the development of the TVT and TVT-O devices, and made summary conclusions

[6] Ex. A at 507:18-517:16; *See also* Ex. A at 476:1-15.

regarding the comparative and long-term data. However, he failed to set forth his opinions in a clearly discernable way. Consequently, it would be extremely difficult to evaluate the reliability of any such opinions. Therefore, any opinions Dr. Murphy may hold regarding the TVT and TVT-O devices (including safety, efficacy and adequacy of the warnings) should be precluded or limited.

VI. Dr. Murphy's General Opinions on the Design and Material Properties of the TVT and TVT-O devices

Dr. Murphy's report does not specifically set forth his opinions as to adequacy of the design and material properties of Ethicon's TVT and TVT-O devices as required by Rule 26(a)(2) of the Federal Rules of Civil Procedure. For the reasons addressed above and in Plaintiffs' Motion, any opinions Dr. Murphy may have regarding the design and material properties of the TVT and TVT-O devices should be precluded or limited.

CONCLUSION

For all of the foregoing reasons, in addition to the arguments set forth in Plaintiffs' Motion, Plaintiffs' *Daubert* motion to preclude or limit the opinions of Dr. Murphy should be granted.

Dated: January 9, 2019.

Respectfully submitted,

/s/ D. Renee Baggett
Renee Baggett, Esq.
Bryan F. Aylstock, Esq.
Aylstock, Witkin, Kreis and Overholtz, PLC
17 East Main Street, Suite 200
Pensacola, Florida 32563
(850) 202-1010
(850) 916-7449 (fax)
rbaggett@awkolaw.com
baylstock@awkolaw.com

CERTIFICATE OF SERVICE

I hereby certify that I filed the foregoing document on January 9, 2019, using the Court's CM-ECF filing system, thereby sending notice of the filing to all counsel of record in this matter.

/s/ D. Renee Baggett
Renee Baggett, Esq.
Bryan F. Aylstock, Esq.
Aylstock, Witkin, Kreis and Overholtz, PLC
17 East Main Street, Suite 200
Pensacola, Florida 32563
(850) 202-1010
(850) 916-7449 (fax)
rbaggett@awkolaw.com
baylstock@awkolaw.com